STATEMENT OF

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Mr. Chairman and Members of the Committee.

I am pleased to be here this morning to present the Administration's views on H.R. 1585, a bill to establish an office to oversee research compliance and assurance within the Veterans Health Administration. We fully support efforts to protect human research subjects, ensure animal welfare and research safety, oversee research compliance, and assure full compliance with research regulations. The Secretary recently approved the establishment of the new independent Office of Research Oversight that is designed to achieve precisely these ends, and we therefore do not believe this legislation is needed. However, should the Committee decide to proceed with this bill, we recommend that several of its provisions be revised.

Mr. Chairman, H.R. 1585 would amend current law to establish an independent office within VHA to oversee research compliance and assurance. The Director of the new office would report directly to the Under Secretary for Health. The mission of the office would be multi-faceted. It would provide counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety. It would also promote and enhance the ethical conduct of

research, investigate allegations of research impropriety and misconduct, and suspend, restrict, or modify research.

Under the bill, the Director of the new office would be responsible for conducting periodic inspections and evaluations of research integrity at VA research facilities, and observing external accreditation site visits for human subjects and animal welfare. The Director would also investigate allegations of research improprieties, endangerment or mistreatment of research subjects, research misconduct, and non-compliance with research policies and regulations. The Director would notify the Under Secretary for Health when endangerment of human research subjects is evident or suspected, and would notify Congress regarding impropriety or misconduct with respect to a VA research project. Other responsibilities would include the advancement of research assurance and compliance activities within VA and with academic affiliates, and the negotiation and maintenance of research assurances with VA medical centers conducting research involving human subjects or laboratory animals. Finally, the bill would direct the Comptroller General of the United States to conduct a study to assess the efficacy of the office, and to report to Congress regarding any recommendations for legislative or administrative changes.

One mission of the new office would be to provide regular counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety. Mr. Chairman, we recommend revising that provision to state that the office would provide regular counsel to the Under Secretary on all *compliance* matters related to these subjects. Within VA, the Office of Research and Development – ORD – is responsible for education, training, and policy matters. In this capacity, the Chief Research and Development Officer regularly advises the Under Secretary for Health on these subjects. Our suggested revision would clarify that the Director of this new office would deal specifically with compliance matters related to these subjects.

The bill also provides that the mission of the new office would include promoting and enhancing the ethical conduct of research. We recommend

modifying that portion of the mission description to clarify that the new office will promote and enhance the ethical conduct of research through its oversight activities, and that the education missions remain with ORD. With regard to this important mission area, the Secretary has recently directed ORD to create the Program for Research Integrity Development and Education – known as PRIDE. The PRIDE program will provide important education, training, and policy guidance to the field.

The bill also provides that the mission of the new office is to suspend, restrict, or modify research, or take other appropriate actions. We recommend revision of that provision to clarify that this type of action would only be carried out with the concurrence of the Under Secretary for Health. Incidents that require the suspension or restriction of research demand the immediate attention of the Under Secretary for Health, whose programs would be directly affected by such action. We also suggest removing the provision stating that the mission of the new office includes the authority to modify research. The Office of Research and Development has responsibility to fund and monitor all research projects and should continue to make significant decisions concerning research protocols and needed modifications to research projects.

Mr. Chairman, this portion of the mission statement goes on to state that the office can take this action to suspend, restrict, or modify research within the context of preserving the integrity and validity of research. Requiring the new office to preserve the validity of research suggests that this office may have responsibility for overseeing the scientific validity of VA research. As mentioned above, this important function should remain with the Director of ORD.

The bill states that the responsibilities of the Director of this new office would include the observation of external accreditation site visits for human subjects and animal welfare. We recommend deleting this provision. Mr. Chairman, the presence of VA central office organizations in any type of external accreditation site visits does not add value to the inspection; rather, it creates coordination problems for the facility, and may even be construed as an attempt by central office to influence the evaluation. Historically, ORD has sent

accreditation reports to the compliance office. I propose to communicate accreditation information to any new compliance office by continuing to send the office copies of all accreditation reports.

As provided in the bill, the duties of the Director would include notifying Congress of any finding of impropriety or misconduct with respect to a research project conducted by the Department. I am concerned about this provision, as it does not follow the chain of command within the Department. We suggest deleting this provision, or revising it to require the Secretary to notify Congress in the case of a finding of impropriety or misconduct with respect to a VA research project involving human subjects or animal welfare.

Mr. Chairman, I am also concerned that this provision, as it is currently written, may lead to the reporting of many incidents of a minor nature that are relatively inconsequential to the protection of human subjects or animal welfare. My experience has shown that some reported problems, when thoroughly discussed and reviewed, are not compliance issues. Day-to-day communication about the status of all ongoing cases may be difficult to manage. It may cause problems, both for Congress and the new compliance office, in assessing the significance and importance of the alleged impropriety or misconduct, and the appropriate actions for responding to the conduct. One option would be to revise the provision to require reporting of serious cases of impropriety or misconduct that lead to a site visit to assess and resolve the incident. A second alternative would be to require the more comprehensive reporting on a quarterly, semi-annual, or annual basis.

As I stated earlier, nearly all of the functions that the bill directs VA to undertake are generally being carried out in VHA, either within the existing compliance office – the Office of Research Oversight – or within ORD.

Mr. Chairman this concludes my testimony. I would be pleased to answer any questions you may have.